The Risk of Pregnancy After Vasectomy

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OBJECTIVE: To describe the pregnancy rates among women whose husbands underwent vasectomy.

METHODS: Between 1985 and 1987, 573 women aged 18–44 years whose husbands underwent vasectomy in medical centers in 5 U.S. cities were enrolled in the U.S. Collaborative Review of Sterilization, a prospective cohort study of male and female sterilization. Women were interviewed by telephone at 1, 2, 3, and 5 years after their husbands underwent vasectomy.

RESULTS: Among the 540 eligible women at risk for pregnancy, there were 6 pregnancies occurring from 6 to 72 weeks after vasectomy. The cumulative probability of failure per 1,000 procedures (95% confidence interval) was 9.4 (1.2, 17.5) 1 year after vasectomy and 11.3 (2.3, 20.3) at years 2, 3, and 5.

CONCLUSION: Couples considering vasectomy should be counseled about the small, but real, risk of pregnancy following the procedure and that men are not sterile immediately after vasectomy. (Obstet Gynecol 2004;103: 848–50. © 2004 by The American College of Obstetricians and Gynecologists.)

LEVEL OF EVIDENCE: II-2

Although vasectomy is believed to be highly effective, pregnancies after vasectomy have been reported.[1–3] The U.S. Collaborative Review of Sterilization (CREST), a prospective, multicenter, observational study of sterilization, has previously reported the risks of pregnancy among women undergoing tubal sterilization.[4] However, the risk of pregnancy among women enrolled in CREST whose husbands underwent sterilization has not been reported. The purpose of this brief report is to describe pregnancy rates among a cohort of women in the CREST study whose husbands underwent vasectomy.

MATERIALS AND METHODS

Detailed methods of the CREST study have been reported elsewhere,[4] including the details of the vasectomy comparison cohort.[5] All enrollees gave written, informed consent, and the study was approved by the institutional review board at each center. Briefly, between 1985 and 1987, 573 women aged 18–44 years whose husbands underwent vasectomy in medical centers in 5 U.S. cities were enrolled in the CREST study. Women were interviewed by telephone 1, 2, 3, and 5 years after their husbands underwent vasectomy and asked if they had been pregnant since their husband's vasectomy. When a woman responded affirmatively, the interviewer then asked additional questions about the pregnancy, and whenever possible, medical records were reviewed. Women were considered at risk for pregnancy only if they were still married to the partner who had the vasectomy (separated or divorced women were censored at date of marital status change) and if they had not had a tubal sterilization or hysterectomy (sterilized women were censored at annual follow-up when sterilization procedure was reported). There were no reports of vasectomy reversals.

Two authors (D.J.J. and H.B.P.) independently reviewed each case in which a pregnancy occurred and estimated the date of conception based on all available clinical information, most of which was provided by the woman whose husband underwent vasectomy (eg, reported last menstrual period, delivery, or termination date). Both authors agreed initially on the classification of failures (true versus preexisting) and reached consensus regarding the estimated date of conception. The number of weeks from vasectomy to the estimated date of conception was calculated. Cases in which the estimated day of conception was before the date of vasectomy are considered preexisting pregnancies. Cases in which the estimated date of conception is after the date of vasectomy are considered true failures. The cumulative probabilities of failure with confidence intervals were

For members of the U.S. Collaborative Review of Sterilization Working Group, see the Appendix.

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Supported by an interagency agreement (3-Y02-HD41075–10) with the National Institute of Child Health and Human Development

0029-7844/04/$30.00
doi:10.1097/01.AOG.0000123246.11511.e4

Table 1. Women With Pregnancies After Husband's Vasectomy

	Preexisting pregnancy at time of vasectomy	Estimated gestational age at time of vasectomy (wk)	True failure	Time from vasectomy to estimated date of conception (wk)
*1	...	...	...	...
2	Yes	3	No	...
3	Yes	4	No	...
4	Yes	5	No	...
5	No	...	Yes	6
6	No	...	Yes	10
7	No	...	Yes	10
8	No	...	Yes	20
9	No	...	Yes	66
10	No	...	Yes	72

* This woman reported a pregnancy at her first-year follow-up visit, but no further information about the pregnancy is available.

calculated for each year up until 5 years by using the product-limit method due to small sample size.

RESULTS

Of the 573 enrolled women whose husbands underwent vasectomy, 29 were excluded from this analysis because there is no follow-up information available (not located or refused). At 1, 2, 3, and 5 years after their husbands underwent vasectomy, the following numbers of women completed a follow-up telephone interview: 511 (94%), 473 (87%), 469 (86%), and 432 (79%), respectively. Enrolled women were predominantly white (91%) and well educated with 60% having 12 or more years of education. Most women (63%) were aged at least 30 years. Table 1 summarizes the 10 pregnancies reported in the CREST study among the 544 eligible women whose husbands underwent vasectomy. In 1 case a woman reported a pregnancy at her first year follow-up visit, but no additional information about the pregnancy is available. In addition, there were 3 women with pregnancies determined to be preexisting at the time the vasectomy was performed; the estimated gestational ages of these pregnancies at the time of vasectomy were 3, 4, and 5 weeks. There were 6 pregnancies classified as true failures. Medical records regarding these pregnancies were available for only 1 of the 6 women. Among the 6 failures, the lengths of time from vasectomy to the estimated dates of conception were as follows: 6, 10, 10, 20, 66, and 72 weeks. Among the couples with true failures, 2 women reported that they subsequently underwent tubal sterilization and 3 men underwent a repeat vasectomy. Although not specifically asked, 2 women spontaneously reported that they and their husband did not follow the urologist's instructions regarding length of abstinence (or use of back-up contraception) following vasectomy and follow-up semen analyses to document sterility. One of these women reported that her husband belatedly had a semen analysis and was told that he was sterile at that time. Among the 6 women with true failures, 4 women chose to continue their pregnancies and had liveborn infants; 2 women chose to terminate their pregnancies.

To calculate the cumulative probability of failure, the woman who reported a pregnancy at 1 year was not included because no information was available regarding her pregnancy. In addition, the 3 women with preexisting pregnancies at the time of vasectomy were not included. Among the 540 women at risk for pregnancy, the cumulative probability of failure per 1,000 procedures (95% confidence intervals) was 9.4 (1.2, 17.5) at 1 year after vasectomy and 11.3 (2.3, 20.3) at years 2, 3, and 5. If it is assumed that the 1 excluded woman with a reported pregnancy indeed had a true failure and that it occurred at 6 months (half way between the interview at the time of sterilization and the first follow-up interview at 1 year), then the cumulative probability of failure per 1,000 procedures would be 11.2 (2.3, 20.1) at 1 year after vasectomy and 13.1 (3.5, 22.8) at years 2, 3, and 5.

DISCUSSION

We found the 5-year failure rates following vasectomy similar to those previously reported following tubal sterilization among women enrolled in CREST[4] and similar to vasectomy failure rates previously reported in 2 other studies.[1,2] However, neither CREST nor any other large cohort study was designed specifically to compare pregnancy rates for vasectomy versus tubal sterilization.

Regarding the timing of vasectomy failures, half of the vasectomy failures in this study occurred during the time (within 3 months) when most providers advise couples to avoid intercourse or use a back-up method of contraception. Although a common recommendation is to have semen analysis performed 3 months after vasectomy or after 20 ejaculations and to avoid intercourse or use temporary contraception until azospermia is documented, the time from vasectomy to azospermia is incompletely characterized and may vary by vasectomy technique.[6–8] Couples should be counseled that men are

not sterile immediately after the procedure and, until the absence of sperm is documented on microscopic examination of the semen (where semen analysis is available), intercourse should be avoided or another method of contraception should be used. Although most vasectomy failures occurred relatively early (within 6 months of the procedure), 2 pregnancies occurred more than a year after the vasectomy. Unlike the findings for tubal sterilization in CREST, in which failures occurred many years after the procedure, all the vasectomy failures in CREST occurred within the first 2 years. Other studies, however, have documented that vasectomy failures do occur more than 2 years after vasectomy.[1–3]

Limitations of this report include the relatively small sample size of the vasectomy group and the fact that the method of vas occlusion is not known. Indeed, 5 of the 6 failures occurred in 1 city (in which 41% of the study vasectomies were performed); we are uncertain regarding whether surgical technique in that city was any different from those in other cities. Furthermore, there have been some changes in vasectomy technique in the intervening years since this study was completed. These changes may affect vasectomy failure rates. Additionally, in the absence of paternity testing, it is not certain that pregnancies that occur to women whose husbands undergo vasectomy are associated with vasectomy failure. Conversely, the vasectomy failure rate would be underestimated if some women conceal and terminate pregnancies that may result from a vasectomy failure. A strength of this report is that CREST participants were enrolled and followed up prospectively in a rigorous research design and survival analysis was used to compute the cumulative probability of pregnancy.

Couples who are considering sterilization should be counseled that both male and female sterilization are highly effective methods of permanent contraception but that pregnancies can occur. When such pregnancies occur, they are more likely to be ectopic after tubal sterilization than after vasectomy. In addition, they should be informed that there are other methods of safe and effective long-term contraception which are also reversible, such as the copper T380A and levonorgestrel-releasing intrauterine devices.

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Received November 4, 2003. Received in revised form January 28, 2004. Accepted February 5, 2004.

APPENDIX

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